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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,405	10/18/2001	Paul O. Sheppard	98-43C1	8125

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,405	SHEPPARD ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims pending: 1-22.

2. Applicant's election without traverse of Group II (claims 7-14) in the Paper filed 12/17/03 is acknowledged.

Claims 1-6 and 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 7-14 *are under consideration in the instant application.*

IDS

3. It is noted that no IDS appears to have been filed in the instant case.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. The disclosure is objected to because it contain an embedded hyperlink at least on page 59 at line 15, page 64 at line 17 and page 65 at line 6. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant is requested to review the application for additional embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See MPEP § 608.01 and 608.01(p).

Claim Rejections - 35 USC §§ 101 and 112 first paragraph

7. 35 U.S.C. § 101 reads as follows:

> *"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".*

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 7-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Neither the nucleic acid comprising SEQ ID NO:1 or SEQ ID NO:3 are supported by a specific and substantial utility. Although the specification discloses on pages 59-60 that chromosomal mapping shows the *Zsig16* gene comprising SEQ ID NO:1 resides in a chromosomal region which includes other genes known to be involved in various diseases, there is no specific utility for linkage-based testing with *Zsig16* nucleotide sequences. No disease association is provided for the *Zsig16* gene itself, and any gene found in that chromosomal region can be utilized in linkage analysis. Because all cDNAs can be used for hybridization, such is not considered a specific utility in the absence of any further characterization. Further experimentation is necessary to attribute utility to the claimed nucleic acids comprising SEQ ID NO: 1 or SEQ ID NO:3.

Neither is a function of the Zsig16 polypeptide of SEQ ID NO:2 (encoded by SEQ ID NO:1 or the degenerate SEQ ID NO:3) or a disease association disclosed in the specification as-filed. Applicant asserts that Zsig16 is a new ligand that binds a natural killer cell inhibitory receptor based upon the observation that mRNA expression of Zsig16 in cell lines shows some correlation with resistance to killer cell mediated lysis (specification page 6). However, no functional or structural data supporting this assertion is disclosed, nor is the particular NK inhibitory receptor identified. Further experimentation is necessary to attribute utility to the claimed Zsig16 polypeptide comprising SEQ ID NO:2 or fragments thereof. Therefore, further experimentation is also required to attribute a specific and substantial utility to the nucleic acid encoding the Zsig16 polypeptide or fragments thereof.

The recited uses also do not constitute a well-established utility because the scientific literature fails to disclose a specific and substantial utility for an isolated nucleic acid of SEQ ID NO:1 (or the degenerate nucleic acid of SEQ ID NO:3) encoding the polypeptide of SEQ ID NO:2 or fragments thereof.

See *Brenner v. Manson*, 383 U.S. 519, 535-36 (1966) which noted that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing". Further, it was stated that, in context of the utility requirement, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

10. Claims 7-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. Even if a specific and substantial utility is established for the nucleic acid of SEQ ID NO:1 or SEQ ID NO:3 encoding the polypeptide of SEQ ID NO:2, the following rejection would apply:

12. Claims 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 recites a nucleic acid that encodes a "Zsig16" polypeptide and hybridizes to a nucleic acid comprising the nucleotide sequence of SEQ ID NO:1.

SEQ ID NO:1 is a coding sequence. A nucleic acid that hybridizes to SEQ ID NO:1 would therefore be the complement of SEQ ID NO:1 (or some variant thereof). The state of art at the time the invention was made recognized that a complement of a coding sequence would not encode a polypeptide having an structural or functional similarities to the polypeptide encoded by the sense nucleic acid. The specification does not appear to provide sufficient guidance as to how the skilled artisan would use a polypeptide encoded by a nucleic acid that hybridizes to the coding nucleic of SEQ ID NO:1. The skilled artisan would therefore not be able to practice the instant invention without undue experimentation.

Claim Rejections - 35 USC § 112 second paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

14. Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 and claims 8-14 depending therefrom are indefinite in the recitation of "stringent conditions" as it is unclear to what conditions the claims are drawn. Stringency of hybridization condition can be considered either "low", "moderate", or "high"; encompass both salt concentrations and temperature of hybridization; and determine the degree of complementarity needed for one nucleic acid molecule to hybridize to another. Absent a clear definition as to these parameters, the claims are indefinite as it cannot be determined what type of hybridization conditions are encompassed by the instant claims, in turn prohibiting a determination of the degree of complementarity possessed by the nucleic acid sequence which hybridizes to the complement of SEQ ID NO:1 or to SEQ ID NO:1.

It is suggested that Applicant amend the claim to more particularly point out the nature of the hybridization conditions by including particular parameters such as those disclosed on pages 26-27 of the specification.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections – 35 U.S.C. §§ 102 and 103

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 7-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Bakker et al. (U.S. Pat. No. 6,416,973, see entire document).

Bakker et al. teach the nucleic acid of SEQ ID NO:7, encoding a polypeptide they name DAP10 (see entire document, especially sequence listing and Table 2 at column 10).

SEQ ID NO:7 of Bakker et al. is also a nucleic acid comprising nucleotides 104 to 325 of instant SEQ ID NO:1 and therefore encodes a polypeptide identical to instant SEQ ID NO:2.

SEQ ID NO:7 of Bakker et al. would hybridize to the complement of SEQ ID NO:1 under stringent conditions. In addition, because SEQ ID NO:7 of Bakker et al. is identical to instant SEQ ID NO:1 from nucleotide 2 to about nucleotide 385, SEQ ID NO:7 of Bakker et al. also is a nucleic acid molecule comprising the degenerate nucleic acid sequence set forth in SEQ ID NO:3 (which encodes instant SEQ ID NO:2)

Bakker et al. teach vectors comprising the isolated nucleic acid encoding a DAP10 polypeptide, including expression vectors with operably linked transcription promoters and transcription terminators, at columns 29-30. Recombinant host cells, including bacterium, yeast, insect, and mammalian host cells, are taught at columns 30-32. methods of using the expression vectors to produce polypeptides are taught at column 32.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention.

The reference teachings thus anticipate the instant claimed invention.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark whose telephone number is (571) 272-0848. The examiner can normally be reached on Monday from 7:30 to 4:00, and on Tuesdays and Thursdays from 10:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 1, 2004

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